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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,292	10/09/2003	Scott Wofford	41650.2	9344

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EXAMINER	
ALTER, ALYSSA M	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/682,292	WOFFORD ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/9/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3-4, 9-12, 18 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Slovak (US 5,058,605). Slovak discloses a multipoint electrostimulation device that generates DC pulses for the treatment of chronic diseases of the locomotor system. The "point electrodes .... are of needle-like shape" (col. 4, lines 49-50), and thus conductive needles. Furthermore the DC pulses may be sawtooth-like, triangular or rectangular with a frequency range of 10Hz to 10kHz, more specifically 250Hz to 5kHz.

As to claim 3, the pulse width in the range of 50 to 250μs.

As to claims 4, 18 and 20, Slovak discloses treatment or rehabilitation in column 9, lines 23-24 that the patient applied therapy 4-5 times during the week. Therefore, there was a cycling between stimulation and rest.

As to claim 9, the delivery of stimulation to the body inherently elicits a visible muscle contraction.

As to claim 10, the area requiring rehabilitation or treatment is identified before therapy, since the electrodes need to be placed in the region requiring therapy prior to the execution of the treatment.

As to claim 11, as seen in figure 1, the conductive needles 3' each has their own connection or lead to the energy source.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 2, 5-8, 19, 23-27, 33-41, 43-44, 49-53, 55, 57-59 and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slovak (US 5,058,605). Slovak discloses the claimed invention but does not disclose expressly the range of pulses per second. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the therapeutic pulses as taught by Slovak, with the ranges of pulses per second because Applicant has not disclosed the range of pulses per second provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the therapeutic pulses as taught by Slovak, because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233 (see MPEP 2144.05).

Therefore, it would have been an obvious matter of design choice to modify with the ranges of pulses per second to obtain the invention as specified in the claim(s).

As to claims 5-8, 25-27, 38 and 40-41, Slovak discloses the claimed invention but does not disclose expressly the specific ranges for the length of time for stimulation/rest cycle, the stimulation cycle segment length and the rest cycle segment length. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the length of time for stimulation and rest segments as well as the length of time for the stimulation/rest cycles as taught by Slovak, with the ranges for the length of time for stimulation/rest cycle, the stimulation cycle segment length and the rest cycle segment length, because Applicant has not disclosed the length of time for stimulation/rest cycle, the stimulation cycle segment length and the rest cycle segment length provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the length of time for stimulation/rest cycle, the stimulation cycle segment length and the rest cycle segment length as taught by Slovak, because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233 (see MPEP 2144.05).

Therefore, it would have been an obvious matter of design choice to modify with the ranges for the length of time for stimulation/rest cycle, the stimulation cycle segment length and the rest cycle segment length to obtain the invention as specified in the claim(s).

As to claims 24, 39, 55 and 57, Slovak discloses the claimed invention but does not disclose expressly the pulse width of 300μs. It would have been an obvious matter

of design choice to a person of ordinary skill in the art to modify the pulses as taught by Slovak, with a pulse width of 300μs, because Applicant has not disclosed the specific pulse width provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the pulses as taught by Slovak, because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233 (see MPEP 2144.05).

Therefore, it would have been an obvious matter of design choice to modify with the pulses to obtain the invention as specified in the claim(s).

As to claims 19, 34, 50 and 64, Slovak discloses the claimed invention except for the length of time the treatment regiment is preformed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the length of time the treatment regiment is preformed as taught by Slovak with a treatment length for at least 3 months or 12 months since it was known in the art to modify treatment regiments to meet specific patient needs. Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233 (see MPEP 2144.05).

2. Claims 13-16, 28-31, 45-48 and 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slovak (US 5,058,605) in view of Jarding et al. (US 6,035,236). Slovak discloses the claimed invention except for the electro-conductive gel. Jarding

teaches that it is known to use conductive gel to administer electrical stimulation as set forth in column 4, lines 41-57, for the purpose of delivering electrical stimulation therapy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the delivery of electrical stimulation as taught by Slovak with the electro-conductive gel as taught by Jarding et al., in order to test and determine the proper position of the conductive needle before insertion. As a result, the patient would not be subjected to improper needle placement and which could cause pain and discomfort.

3. Claims 17, 32, 42, 54 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slovak (US 5,058,605) in view of Fabian et al. (US 5,431,625). Slovak discloses the claimed invention except for the current ramping. Fabian et al. teaches that it is known to utilize ramping of current as set forth in column 1, lines 32-50, for the purpose of minimizing the shocking or stunning sensation a patient may receive during rapid changes in current level. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the delivering of pacing pulses as taught by Slovak with a ramping of current as taught by Fabian et al., in order to minimize patient discomfort during the application of electrotherapy.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M. Alter

Alyssa M Alter
Examiner
Art Unit 3762

JEFFREY R. JASTRZAB
PRIMARY EXAMINER
1/9/6